## REMARKS

In the Office Action mailed July 24, 2008, claims 1, 2, 13-15, 20-24, 29-33, 38, and 39, and 42-65 were pending for consideration. Claims 44-65 remain withdrawn from consideration. All of the claims were objected to and/or rejected on various statutory grounds, each of which is addressed in turn below. By the present amendment, claims 1, 32, and 33 have been amended to reintroduce tocopherol polyethyleneglycol succinates into the lists of possible solubilizers and/or release solubilizers as were present in the previously pending claims. Additionally, claims 1, 32, and 33 were each amended to include the limitation that less than 50% of the drug be released after 2 hours. Support for the limitation can be found *inter alia* throughout the originally filed specification including FIGS 2, 4, 5, 8, and 9 as well as corresponding formulations present in Examples 2, 4, 6, 9, and 13. Applicants submit that the described formulations and the associated data presented in the FIGS 2, 4, 6, 9, and 13 provide ample support for the scope of the presently amended claims. Applicants submit that no new matter has been added through this or any previous amendment of the claims.

It is to be understood that all amendments have been made solely for the purpose of expediting prosecution of the present application, and without conceding the correctness of the Examiner's rejections. Accordingly, claims 1, 2, 13-15, 20-24, 29-33, 38, and 39, remain pending. Applicants respectfully submit that the present claims are allowable over the cited references, and that the rejections in view thereof are now moot.

35 U.S.C. § 102 Rejections:

The Examiner has rejected claims 1, 13-15, 20-24, 29, 32-33, 38, and 42-43 under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Pat. No. 5,891,469 (hereinafter

"Amselem"). As discussed above, the presently pending claims have been amended to include the limitation that less than 50% of the drug be released within 2 hours. Such a limitation is not taught in Amselem. Each of the compositions shown in Amselem provides a release profile which would be considered by those of ordinary skill in the art to be an "immediate release" profile. Such profiles clearly show that well in excess of 50% of the active agents in the various formulations are released within the first two hours. In fact, the immediate release profiles shown in Amselem's FIG 1 all show in excess of 50% release of the active agent within about the first 10 minutes. Amselem even heralds the rapid release of provided by its formulations. For Example, in describing the release profiles of the formulations shown in FIG 1, Amselem states: "[d]epending on the specific composition of the formulation, very good Dexanabinol release (from 60-95%) was obtained – mainly during the initial 10-20 minutes. (emphasis added) (col. 9, lines 59-61) Another example of Amselem hailing the rapid release characteristics of its composition is found in Example 7, where a marketed (preexisting) product was compared to the claimed composition by stating "[t]he release of CoQ10 from the marketed product was very low compared to a very quick and significant release from the powdered TPGS/PVP coprecipitate formulation." (emphasis added) (col. 12, lines 24-26). Applicants assert that such passages as well as the figures of Amselem are unambiguous in their teachings that the compositions taught by Amselem have release characteristics which are "very quick" or immediate. As such, Applicants respectfully submit that the cited reference does not teach each and every element of the pending clams, and therefore it is respectfully requested that this rejection be withdrawn.

35 U.S.C. § 103 Rejections

The Examiner has rejected each of the pending claims under 35 U.S.C. § 103(a) as being allegedly unpatentable over the U.S. Patent No. 5,891,469 to Amselem et al. (hereinafter "Amselem") patent in view of either The Merck Index (Eleventh Edition, Monograph 3924, 1989; pages 624-625) or U.S. Patent No. 3,097,144 to Banker (hereinafter "Banker"). As discussed above, Amselem teaches a solid dry coprecipitate of lipophilic active ingredients and which requires tocopherol polyethyleneglycol succinate (TPGS) and which provide immediate release of the active ingredient. However, Amselem does not teach delivering a drug or active agent over an extended period of time or with the release characteristics required by the presently pending claims.

The Examiner has asserted that because Amselem showed various formulations which showed release of an active agent gradually increasing over the course of 120 minutes, such release constituted extended release over a period of time of 2 hours. Without conceding the correctness of such an assertion and merely to advance prosecution of the claims, Applicants have amended the claims to require that less than 50% of the drug in the formulation be released within the first two hours.

Each of the compositions shown in Amselem provides release profiles which would be considered by those of ordinary skill in the art to be "immediate release" profiles. As discussed above, such profiles clearly show that well in excess of 50% of the active agents in the various formulations are released within the first two hours. Accordingly, as discussed with the Examiner in the telephonic interview of October 30, 2008, Applicants assert that Amselem fails to teach or suggest of composition which provides release over an extended period of time of 2 to 24 hours and which releases less than 50% of the drug in the formulation within the first two hours. Such elements are also not taught in the secondary references of the rejection.

Further, Applicants assert that, upon review of the teachings of Amselem (e.g. the above passages), one of ordinary skill in the art would be disincentivised from using the formulations taught by Amselem to formulate a product or composition which had the presently claimed release characteristics, namely being released over an extended period of time of 2-24 hours and releasing less than 50% of the drug within the first 2 hours. In other words, Applicants assert that Amselem's teachings effectively teach away from the use of the taught compositions in formulating products having the presently extended release characteristics.

As the Applicant has raised the issue of teaching away, the Applicant would like to review the current case law regarding teaching away for the Examiner's convenience. The Court of Appeals for the Federal Circuit has clearly stated that "an applicant may rebut a prima facie case of obviousness by showing that the prior art teaches away from the claimed invention in any material respect." In re Petersen, 315 F.3d 1325, 1331 (Fed. Cir. 2003). The Court has also stated that "[w]e have noted elsewhere, as a 'useful general rule,' that references that teach away cannot serve to create a prima facie case of obviousness." (emphasis added) McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1354 (Fed. Cir. 2001). In identifying the appropriate standard for teaching away, the Court has further stated:

> "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be **discouraged from following the path set out in the reference**, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, **a reference will teach away if it suggests** that the **line of development** flowing from the reference's disclosure **is unlikely to be productive** of the result sought by the applicant." (emphasis added) In re Gurley, 27 F.3d 551, 553 (Fed. Cir. 1994).

Clearly in the present case, a person of ordinary skill in the art would be disincentivised (i.e. led away) from preparing a formulation which was intended to provide release over an

extended period of time of 2 to 24 hours and which would release less than 50% of the drug within the first two hours.

In light of the above arguments, Applicants submit that the combination of Amselem and Merck fails as well as the combination of Amselem and Banker fail to present a *prima facie* case of obviousness in that the references taken together fail to teach each and every element of the pending claims, namely a composition which includes compositions which have at least one of the presently claimed solubilizers and at least one of the presently claimed release modulators which provides extended release over a period of time of 2 to 24 hours and which releases less than 50% of the drug in the first two hours. Further such, Applicants assert that the combination of references fails to render the presently pending claims obvious because one skilled in the art would be disincentivised from making the presently claimed compositions using the compositions in Amselem due to their characteristic of providing rapid release of the active agent. Accordingly, it is respectfully requested that the rejection be withdrawn and the claims be allowed.

## CONCLUSION

In view of the foregoing, the Applicants believe that claims 1, 2, 13-15, 20-24, 29-33, and 38-39 present allowable subject matter and the prompt allowance thereof is requested. If any impediment to the allowance of these claims remains after consideration of the present amendment and above remarks, and such impediment could be removed during a telephone interview, the Examiner is invited to telephone the undersigned attorney, so that such issues may be resolved as expeditiously as possible.

Please charge any additional fees except for Issue Fee or credit any overpayment to Deposit Account No. 20-0100.

Dated this 14th day of November, 2008.

Respectfully submitted,

THORPE, NORTH & WESTERN, LLP

David W. Osborne
Reg. No. 44,989
8180 South 700 East, Suite 200
Sandy, UT 84070
Telephone: (801) 566-6633
Facsimile: (801) 566-0750

DWO/PSS:ja